



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFZ-35  
536  
Public Health Service  
Cincinnati District

Food & Drug Administration  
1141 Central Parkway  
Cincinnati, OH 45202-1097

August 14, 1997

**WARNING LETTER**  
**CIN-WL-96-598**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Scott A. Johnson, President  
Basic Organics, Inc.  
885 Claycraft Road  
Blacklick, OH 43004

Dear Mr. Johnson:

This letter is in reference to your firm's marketing and distribution of the products, "Super Guarana 1000mg", "Natural Papaya Enzyme", and "Enzymatic Digestant" that are being promoted as aids to digestion, mental alertness, and weight control.

Based on intended use, your product, "Super Guarana 1000mg" is a drug subject to the Final Monograph for Over The Counter (OTC) stimulant drug products under Title 21, Code of Federal Regulations (CFR), Part 340. Your product contains ingredients not approved in the Final Monograph for this purpose and it is, therefore, an unapproved new drug.

In addition, your labeling for the products, "Natural Papaya Enzyme" and "Enzymatic Digestant" claims that these products are aids to digestion. As such, they are drugs subject to the Final Monograph for OTC digestive aids as described in 21 CFR 310.545(a)(8). These products contain ingredients that were declared not safe and effective in the Final Monograph and therefore, these products are unapproved new drugs.

"New drugs" as defined in Section 201(p) of Federal Food, Drug and Cosmetic Act (the Act) may not be legally marketed in the United States without approved New Drug Applications as stated in Section 505 of the Act.

These drugs are also misbranded as described in Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use and because the labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established as stated in Section 502(a) of the Act.

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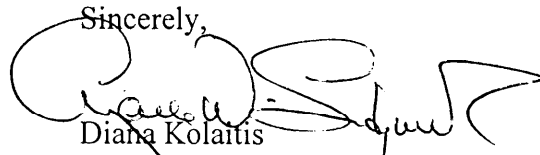
This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Ms. Evelyn D. Forney, Compliance Officer; Food and Drug Administration; 1141 Central Parkway; Cincinnati, OH 45202-1097.

Sincerely,



Diana Kolaitis  
Acting District Director,  
Cincinnati District